Remote Navigation for Ablation Procedures – A New Step Forward in the Treatment of Cardiac Arrhythmias

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Abstract

Catheter ablation has become the curative treatment for various cardiac arrhythmias, including ventricular tachycardia and atrial fibrillation, leading to more challenging procedures, prolonged fluoroscopy exposure and the need for stable and reproducible catheter movement. In the last decade, remotely-controlled catheter ablation has emerged as a novel concept to improve catheter manoeuvrability and stability. This has the potential to increase procedural success, decrease procedure time and minimise catheter-related complications. To date, two remote navigation systems (Niobe from Stereotaxis and Sensei from Hansen Medical) are commercially available based on magnetic and mechanical driven forces, respectively. Both have shown promise but also shortcomings during clinical evaluation. Recently, two new systems, CGCI-Maxwell from Magnetecs and Amigo from Catheter Robotics, have shown promising results in animals. They are under clinical evaluation and are also based on magnetic and mechanical driven forces, respectively. This article describes the basic principles of the systems, summarises their respective published experiences during mapping and ablation procedures, their current clinical applications and future directions.

Keywords

Atrial fibrillation, catheter ablation, robotic, magnetic, remote navigation

Disclosure: Eli S Gang has equity interest in Magnetecs, Inc. Bich Lien Nguyen and Jose L Merino are consultants to Magnetecs, Inc.

Received: 5 August 2010 **Accepted:** 26 August 2010 **Citation:** *European Cardiology*, 2010;6(3):50–6

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Catheter ablation has become the curative treatment for various cardiac arrhythmias. Extending the indications from simple supraventricular tachycardias to complex arrhythmias such as ventricular tachycardia or atrial fibrillation (AF) has led to more challenging procedures. These procedures have prolonged fluoroscopy exposure and the need for stable and reproducible catheter movement. Therefore, the need arose for technical innovations designed to improve catheter stability and manoeuvrability in order to increase procedural success, decrease procedure time and minimise catheter-related complications.[1] In the last decade, remotely-controlled catheter ablation has emerged as a novel concept to meet these requirements.[2–4] Two remote navigation systems (Niobe from Stereotaxis and Sensei from Hansen Medical) are currently commercially available. The mapping catheter is remotely operated by magnetic forces in the former system and by mechanical force applied from a robotic sheath for the latter. Both systems have shown promise but some shortcomings were observed during their clinical evaluation.

Recently, two new systems have been developed. The Catheter Guidance, Control and Imaging-Maxwell (CGCI) from Magnetecs Inc. also operates using magnetic fields. It has shown promising results in animals and is currently under clinical evaluation. The Amigo remote catheter system from Catheter Robotics Inc. operates conventional catheters using mechanical forces. It has demonstrated the ability to facilitate catheter positioning during electrophysiology studies in dogs.[5] No published clinical reports are available so far and a clinical trial is currently being initiated. This article describes the basic principles of the systems and summarises their respective published experiences during mapping and ablation procedures, their current clinical applications and the future directions of these technologies.

The Niobe Magnetic Navigation System

The technology used in the Niobe magnetic navigation system (MNS) has been described in several papers.[2,6] In brief, a low-intensity magnetic field (0.08T) is applied by two large permanent magnets positioned on each side of the patient's body to create a uniform magnetic field within the chest (see *Figure 1*).[3] Catheters with permanent magnets affixed to their distal portion can be navigated within the cardiac chambers by changing the orientation of the magnetic fields, which are controlled by computer-aided mechanical movements of the external permanent magnets. The distal portion of the catheter becomes aligned parallel to each newly applied magnetic field orientation. Since the magnetic fields are changed by mechanical movements within this MNS, a delay occurs between designation of the magnetic field vector and catheter movement within the heart. Another mechanical aspect of the system is a computer-controlled catheter advancer system used for catheter slack control. Published reports using this technology have utilised a 4mm tip catheter with three embedded magnets (Navistar-RMT). An open-irrigated 3.5mm tip magnetic catheter (Thermocool Navistar-RMT) was initially withdrawn from the market because of safety concerns, but has more recently been re-introduced for clinical use.[7] This re-designed catheter has two of the magnets placed proximally to the ring-electrodes and a new location for the irrigation ports in order to decrease the likelihood of char formation during radiofrequency application. These magnet-tipped catheters were designed to allow combined use with a 3D electroanatomical mapping (EAM) system (CARTO RMT, see *Figure 1*). As reviewed below, a variety of arrhythmias have been successfully targeted using the EAM system. Despite this, the results in patients with AF and atrial flutter, the two most frequently ablated arrhythmias, have been mixed.[3,6–9] The absence of true closed-loop integration with an EAM system, lack of realtime catheter response and mixed clinical results are some of the drawbacks of the current MNS.

The Sensei Robotic Navigation System

The operation of this robotic navigation system (RNS) has been described in detail.[4,10] This system controls catheter navigation by steerable sheaths (14 French [Fr] outer and 10.5Fr inner sheaths), through which any conventional ablation catheter can be inserted. The entire assembly is manipulated within the heart via a pull-wire mechanism by a robotic arm fixed at a standard fluoroscopy table. The robot arm obeys the commands of the central computer workstation positioned in the control room, changing the tension applied to wires embedded within these sheaths. Catheter navigation is achieved using a 3D joystick (Instinctive Motion Control) and allows a broad range of motion in virtually any direction. All EAM systems may be used, although the system is mostly used in conjunction with the NavX EnSite™ system (see *Figure 2*). Initial clinical studies showed the feasibility of using this RNS in ablating human AF.[4] Shortcomings of the current system include:

- a very large trans-septal outer sheath;
- scattered reports of a high initial complication rate,[11] i.e. a relatively 'steep' learning curve; and
- the inability, as currently configured, to navigate within important cardiac structures such as the left ventricle and the coronary sinus.

The Catheter Guidance, Control and Imaging Magnetic Navigation System

The CGCI MNS consists of eight coil-core electromagnets arranged semi-spherically around the chest on a standard fluoroscopy table. This generates a shaped ('lobed') dynamic magnetic field focused within the region of the heart of approximately 15cm^3, with a maximal uniform field strength of 0.14T (see *Figure 3*). Rapid (msec) changes in the magnetic field magnitude, direction and gradient yield near realtime push/pull and/or torque (bend) movements in the distal portion of a newly designed magnetised 7Fr 4mm tip radiofrequency Maxwell catheter. The catheter tip is aligned parallel to the vector direction of the magnetic flux density. The magnetic field gradient generated for force control of the catheter is up to 0.7T/meter, with a maximal perpendicular force exerted of 25g. A special trans-septal sheath with electrodes along its distal end (Agilis ES) permits compensation for catheter sheath movements arising from the motion of the interatrial septum. The CGCI system is a closed-loop servo system that is fully integrated with a 3D EAM system (EnSite NavX). It also incorporates an obstacle-avoiding artificial intelligence routine for navigating obstacles within cardiac chambers (see *Figure 3*). Published experience with this system has been limited to initial animal studies.[12]

The Amigo Remote Catheter System

This remote catheter system is intended to facilitate the manipulation, positioning and control of standard and familiar diagnostic and ablation catheters by loading them into the device at any time during the procedure. It comprises a mechanical catheter manipulator or robot and a remote control handle that enables the user to manipulate a standard, conventional electrophysiology catheter. This catheter has previously been inserted into patients through the full range of its three functions:

Figure 1: Niobe™ Magnetic Navigation System

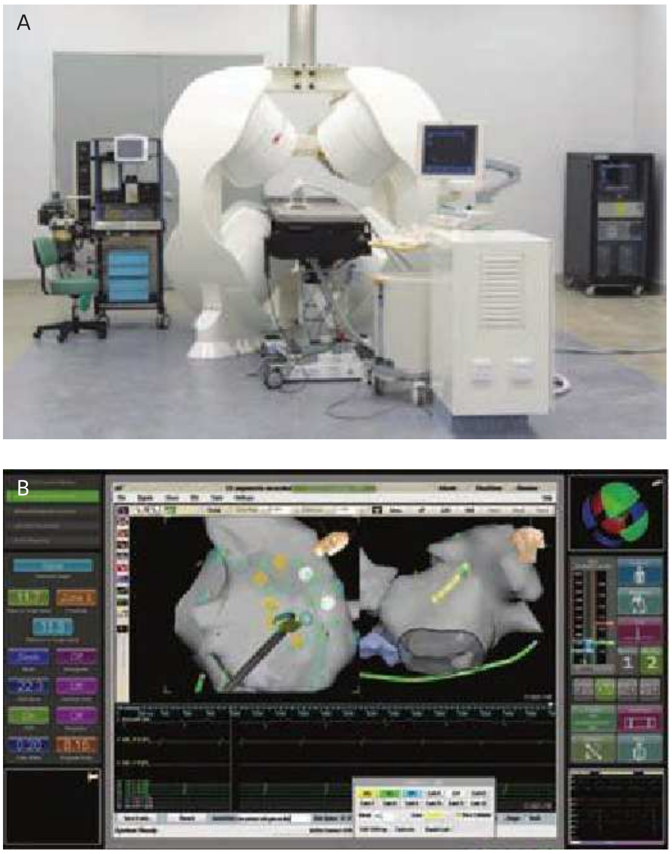
A: The Niobe™ Magnetic Navigation System. B: Niobe-Carto interface screens during a left atrium procedure.
Courtesy of Dr Fernandez-Lozano, Madrid.

Figure 2: Sensei Robotic Navigation System

A: Sensei™ robotic navigation system interface screens with EnSite NavX during atrial fibrillation ablation (Courtesy of Dr Moya, Barcelona). B: Range of movements of the sheath-catheter assembly in the left atrium.

- insertion/withdrawal;
- deflection; and
- rotation.

Figure 3: The CGCI Magnetic Navigation System



A: CGCI-Maxwell™ magnetic navigation system. B: CGCI-NavX overlay screen, showing the ablation catheter within the NavX geometry during a left atrium procedure

When used in conjunction with an EAM system, X-ray exposure can be reduced for physicians and the patient, thereby creating a safer work environment. This device is designed to operate with a variety of catheters for different applications, but so far it only operates with Biosense Webster and Boston Scientific catheters. The system is assembled in about 30 minutes. It sits at the foot of the bed, can be placed in an existing operating room and easily be moved out of the way when not in use. The learning curve with use is hours rather than weeks. The catheter's handle and shaft can be quickly disengaged from the robot (without removing the catheter from the patient's body). This allows the operator to quickly gain manual control of the catheter if for any reason this should be necessary. The catheter can subsequently be re-engaged with the robot to switch back to remote manipulation within seconds and without difficulty (see *Figure 4*). All of this can be achieved without affecting catheter sterility. Published experience using this system *in vivo* is limited to one animal study.[5]

Experience using Remote Navigation Systems

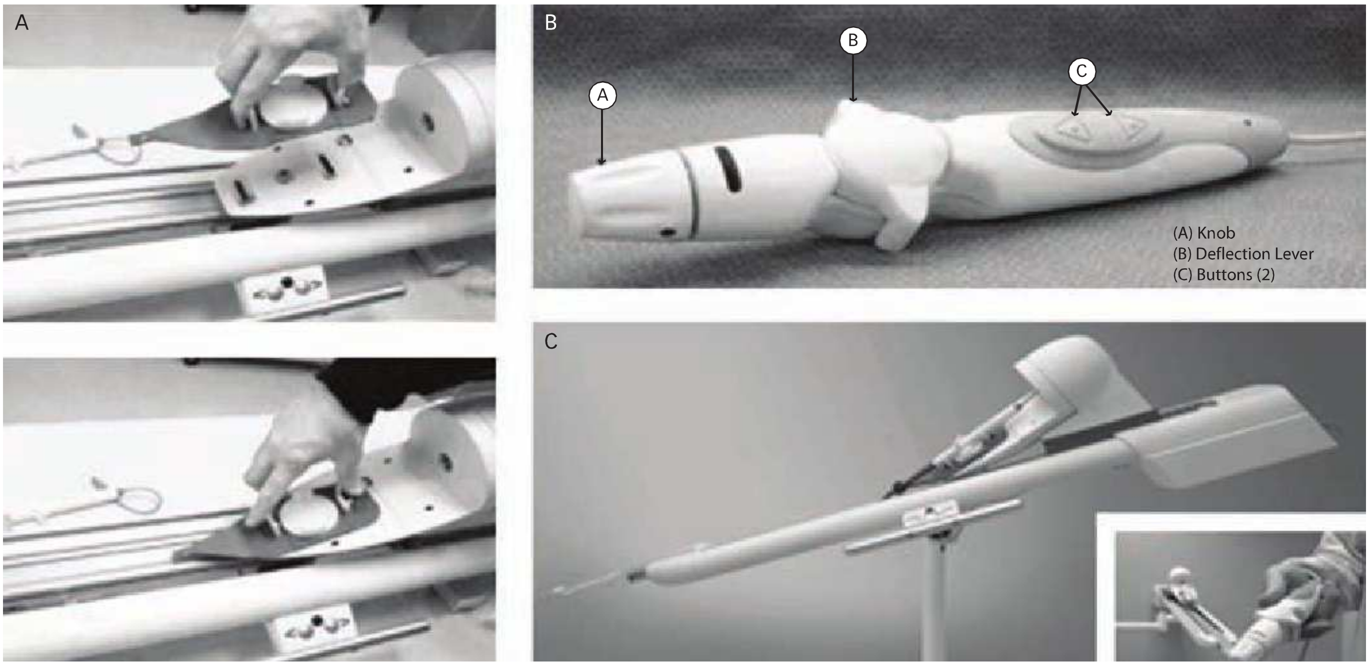
Initial reports describing Niobe MNS technology were published in 2002.[2] The technology proved to be a safe and effective tool in the treatment of supraventricular and ventricular arrhythmias.[6,8,9,13–20] Slow pathway modification can be achieved with lower temperatures and powers, earlier time to junctional rhythm and less variability of temperature during ablation. This suggests enhanced catheter stability and substrate contact compared with manual ablations in patients with atrioventricular nodal re-entrant tachycardia (AVNRT).[21,22] Cavotricuspid isthmus (CTI) radiofrequency ablation using this system in patients with CTI-dependent atrial flutter is characterised by shorter fluoroscopy times.[9] However, it was also associated with a significantly lower success rate, longer ablation times and a larger number of radiofrequency energy applications. This was probably due to the lower maximal endocardial forces exerted, resulting in inadequate lesion formation compared with conventional manipulation. These observations suggest that focal radiofrequency ablations benefit more from Niobe MNS than linear radiofrequency ablations.

In recent years, the issue of pulmonary vein isolation during AF ablation has been addressed. Pulmonary vein isolation using a non-irrigated 4mm tip catheter was performed at different centres.[3,8] In one of these studies, Di Biase et al. reported satisfactory results with regard to navigation properties of the MNS, but failed to achieve complete pulmonary vein isolation in 92% of the patients when using the Niobe MNS.[8] Lack of sufficient lesion depth achieved with the MNS was thought to account for the poor results reported in this study. Extensive charring at the catheter tip was observed in one-third of patients and argued against the use of this catheter within the left atrium (LA).[8] Pappone et al. confirmed Niobe MNS manoeuvrability but did not assess pulmonary vein isolation using a circular mapping catheter.[3]

Finally, a recent study using two iterations of an irrigated magnetic catheter showed a reasonable success rate in the initial isolation of pulmonary veins with a redesigned catheter yielding an acceptable safety profile.[7] Of note, the ability of MNS to perform pulmonary vein isolation using a retrograde approach has been reported.[23] This is a technique not otherwise possible with conventional manipulation. The experience of Niobe MNS-guided ventricular tachycardia ablation has been encouraging. The technology seems to be a feasible and safe mapping and radiofrequency ablation tool for the treatment of ventricular arrhythmias using non-irrigated 4 or 8mm tips and 3.5mm open-irrigated magnetic catheters. Success rates were significantly higher with the 8mm tip than the 4mm tip (59 versus 22%) in patients with structural heart disease and similar (≥85%) in patients with no structural heart disease.[24] The newly available irrigated tip catheter was shown to effectively ablate scar-related ventricular arrhythmias in patients with ischaemic cardiomyopathy with minimal radiation exposure.[25]

In addition, a large series of consecutive patients undergoing endo- and epicardial radiofrequency catheter ablation of ventricular arrhythmias demonstrated the effectiveness of the irrigated catheter with similar success rates (≥85%) to manual ablation at >11 months follow-up. Patients included were with or without structural heart disease. There was a shorter fluoroscopy time (26 minutes), but the use of the irrigated catheter was associated with longer procedure (three hours) and radiofrequency time (33 minutes) than manual ablation.[26] First reports on RNS stated the feasibility and safety of performing trans-septal punctures and LA navigation.[27] RNS has also been used for the ablation of supraventricular tachycardias and AF.[28] RNS-guided radiofrequency ablation in patients with common-type atrial flutter achieved complete bidirectional CTI block in all patients without complications. There was a shorter period of X-ray exposure (eight minutes) and the radiofrequency duration was consistent with increased catheter stability and radiofrequency application efficacy compared to a conventional procedure. However, procedure time was still longer (79.2 versus 58.4 minutes) than manual ablation.[29] Reddy et al.[4] reported complete pulmonary vein isolation using RNS in all patients without serious complications. Long procedure times (>300 minutes) were again observed.

Figure 4: Amigo™ Remote Catheter System



A: Changing the catheter dock on the Amigo's Turret. B: Remote control handle. C: Amigo remote catheter system assembled (remote control shown inset).

In contrast to these results, a recent study showed that RNS-guided pulmonary vein isolation was achieved without complications using shorter procedure times (180 minutes) and limited fluoroscopy. The study had similar success rates to conventional ablation approaches and electrical conduction recovery in 43% of all pulmonary veins after three months.[30] Currently, catheter technology is focusing on the use of pressure sensors to improve the safety and efficacy of radiofrequency applications and to confront the initial concern of an increased perforation risk due to the lack of tactile feedback, but no data are yet available.[31] Published *in vivo* experience using the Amigo system is limited to one study in dogs.[5] This study shows that the use of this catheter manipulator system allows clinicians to remotely position an electrophysiology catheter in target locations within the heart. Adequate endocardial contact measured by pacing thresholds was obtained without causing untoward effects such as cardiac perforation or injury.[5] Remote manoeuvering of catheters approximates the location of the standard catheter at the right atrial appendage, high right atrium and/or lateral right atrium, right ventricular outflow tract and high right ventricular septum.[5] It also records the His bundle electrogram amplitude. The system allows the catheter to be quickly switched between robotic and manual manipulation without losing the position of the catheter tip or affecting the sterility of the catheter.[5] Clinical trials in humans are planned to confirm the results of this animal study. In humans, the robot should allow movement of the catheter from outside the operating room, avoiding staff exposure to the X-rays and speeding up the process. A first clinical trial has been initiated to evaluate the safety and efficacy of the Amigo system and further information is available online (http://clinicaltrials.gov/ct2/results?term=NCT01139814). The trial will analyse its performance for mapping of the right heart (atrium and ventricle) during right-sided electrophysiology diagnostic and ablation (e.g. atrial flutter, AVNRT, right-sided accessory pathway or ventricular tachycardia). The primary outcomes include navigation and mapping performance and safety evaluation of major complications that are definitely or probably related to Amigo-controlled mapping. Secondary outcomes are:

- per-subject performance of the Amigo controlled navigation and mapping;
- total fluoroscopy time with the Amigo system; and
- total procedure time with the Amigo system.

Experience using the CGCI MNS is limited to one animal study.[12] Data obtained from 10 pigs showed that right atrial and LA navigation, mapping and ablation can be safely and effectively performed. A typical CTI radiofrequency ablation lesion set was created. Third-degree atrioventricular block was obtained by ablating at the His bundle. LA and pulmonary vein mapping was performed easily within a relatively short time (30 minutes) and there was a trend towards shorter mapping times as operator proficiency increased.[12]

The stability of the CGCI catheter allowed facile navigation within the LA, along the circumference of the mitral valve and within the pulmonary veins despite the relatively small size of the porcine atria and the typically short distance between the trans-septal puncture and the posterior LA wall.[12] Pulmonary vein isolation was achieved when attempted with the non-irrigated 4mm tip special magnetic catheter. No system-related complications were described with CGCI.[12] Radiofrequency ablation was used for 'tagging' the anatomical sites to which the magnetic catheter was navigated and was not intended to deliver transmural radiofrequency lesions. Nonetheless, the majority of the radiofrequency lesions were transmural and visible at necropsy on the epicardial surface, with an overall radiofrequency lesion depth of 78.5±12.1% of the entire LA wall thickness.[12] Non-transmurality was seen at LA appendage trabeculated tissue, where the tissue thickness exceeded that found at the pulmonary vein-LA junction or at the ostia of the pulonary veins. Linear and circumferential radiofrequency lesions were uniformly situated around the pulmonary vein ostia, roof and mitral isthmus, mimicking a typical AF ablation procedure.[12] A clinical trial is under way that will evaluate the accuracy and safety of navigating the magnetic catheter within the four chambers of the heart in patients undergoing left- or right-sided mapping procedures.

Table 1: Overview of the Characteristics of the Four Main Remote Navigation Systems

	Amigo (Catheter Robotics)	Sensei (Hansen Medical)	Niobe (Stereotaxis)	CGCI-Maxwell (Magnetecs)
Action principle	• Robotic catheter manipulation system	• Robotic sheath	• Permanent magnets	• Electromagnets
Operating room conditions	• Portable • No special requirements	• Portable • No special requirements	• Fixed installation • Reinforcement of the floor structure • Room magnetic shielding	• Fixed installation • Reinforcement of the floor structure • No magnetic shielding required
Marketed	• Not yet (research only)	• Yes	• Yes	• Not yet (research only)
Applications	• Potentially all cardiac chambers mapping and ablation • Potential endocardial/ epicardial mapping and ablation	• SVT, AF ablation • Limited to atrial mapping and ablation • Only endocardial	• SVT, AF, VT ablation studies have been published • All cardiac chambers mapping and ablation • Endocardial/epicardial mapping and ablation • Retrograde approach for PVI • CS CRT lead placement • Coronary interventions	• Potential for mapping and ablating all cardiac arrhythmias • Potential for all cardiac chambers mapping and ablation • Potential for endocardial/ epicardial mapping and ablation • Potential for CS lead placement and coronary interventions
Advantages	• Use with any 3D mapping system • No fidelity devices distortion	• Catheter stability • Use with any 3D mapping system • No fidelity devices distortion	• Low risk of perforation • Semiautomated mapping • Numerous clinical trials published • No fidelity device distortion	• True closed loop servo system • Full integration with a 3D-mapping system • Near realtime catheter movement • Catheter stability • Low risk of perforation • Semiautomated and automated mapping • No fidelity devices distortion
Limitations	• Restricted to biosense-Webster and Boston Scientific catheters	• Outer sheath diameter and length (No access to ventricles and CS) • No catheter restriction	• Possibly patients with implanted devices • Non-realtime movement • Restricted to magnetic catheters	• Possibly patients with implanted devices • Restricted to magnetic catheters
Future directions	• Clinical evaluation • Catheter brand expansion chambers	• Smaller sheath • Expand use to all cardiac	• Automapping • Catheter technology	• Clinical evaluation • Catheter technology

AF = atrial fibrillation; CS = coronary sinus; PVI = pulmonary vein isolation; SVT = supraventricular tachycardia; VT = ventricular tachycardia.

Technical Advantages and Disadvantages of Remote Navigation

Table 1 summarises the characteristics of the main remote navigation systems.

The Niobe Magnetic Navigation System

Niobe MNS appears to be a safe technology. Magnetic catheters are by necessity soft, so that chamber wall perforation due to excessive catheter pressure is very unlikely. This may be particularly advantageous in mapping atrial and ventricular arrhythmias, as demonstrated by clinical studies.[32] Moreover all cardiac chambers, including the coronary sinus and epicardial space, have been successfully accessed and mapped.[19] Software features include: storage of prior magnetic vectors, 'design' lesion set concept and a semiautomated mapping feature. Beyond catheter ablation, MNS has been used for the implantation of left ventricle leads in the coronary sinus and for wire navigation in coronary vessels.[33,34] Shortcomings include navigation to distinct sites. For example, the anterior-inferior ostium of the septal pulmonary veins is still difficult to access in some cases, possibly owing to catheter design. Procedure times are still very lengthy. This is likely to be due to ineffective ablation lesions and the delay in catheter movement inherent to this system. The current Niobe MNS is limited to the use of CARTO as the EAM system. There are two limitations specific to the nature of the permanent external magnets. First, patients with implanted devices should not be exposed to the magnetic field in order to avoid device malfunction as published data remain controversial.[35] Second, installation of the magnets in an existing catheter-laboratory requires special room shielding and regulation because of the significant permanent magnetic field.

The Hansen Robotic Navigation System

The Hansen RNS also seems to be safe in experienced hands. Virtually all mapping catheters and EAM systems can be used with RNS and the presence of implanted devices does not limit its use. In early clinical studies, the initial concern was the increased risk of perforation compared with conventional manipulation.[8,10,11] However, recent reports have demonstrated the feasibility of performing RNS-guided pulmonary vein isolation without major complications.[4]

To date, no data on the use of RNS for ventricular arrhythmias are available. Due to the large diameter of the outer sheath and the potential risk of perforation, the coronary sinus and/or epicardial space might not be entered. This could limit the application of RNS in patients with long-standing persistent AF and/or epicardial ventricular tachycardia. Three further arguments could limit the use of RNS for ventricular tachycardia. A 14Fr vascular access is needed, which restricts the approach of the left ventricle to a trans-septal route. The reach of the inner sheath may be too short to map all parts of the left ventricle, unless the 14Fs outer sheath is inserted far into the LA andhe restriction to a distal bipolar recording because the mapping catheter has to be retracted to the inner sheath to achieve optimal stability. To date, RNS does not provide automatic features.

The Amigo

The Amigo system design preserves the normal safety mechanism of catheter buckling when excessive axial force is applied to the catheter handle during either remote or manual manipulation. Other systems that encase almost the full length of the catheter in a rigid steerable sheath lose this important characteristic. This system only applies forces to the catheter handle and thereby utilises the standard catheter mechanisms developed for catheter manipulation: deflection, rotation, catheter advancement and withdrawal. However, other systems apply forces to the catheter by other means. These make the catheter a more passive element in the system. The Amigo system does not have a control station, but instead uses a handheld remote control that closely resembles a standard catheter handle. Its simplicity has the promise of a less costly robotic alternative.

The CGCI MNS

Initial studies using CGCI MNS showed it to be a safe modality in the animal setting for atrial mapping and ablation. The system provides an automated mode for geometry creation and to perform focal, linear and circumferential radiofrequency ablation lesion sets. When operating in the 'automatic mode', the system continuously adjusts for repetitive learned movements of the heart and for anatomical barriers. It keeps the catheter tip on a desired target by continuously adjusting the direction and intensity of the magnetic fields. In the initial CGCI study, the automated catheter remote navigation was highly reproducible (96%), accurate (1.9mm) and rapid (11 seconds). The uniquely shaped magnetic 'lobe' allows enhanced contact with the tissue by pushing the tip firmly against the surface. It has nearly instantaneous field vector adjustments in terms of direction and intensity for the torque, bending or rotating effect and a field gradient for axial push-pull movement. This may translate into more effective lesions than have been reported using the other MNSs available. Despite the known limitations of working within the pig's heart,[36] the ability of this system to reproducibly, accurately and effectively acquire targets and realtime 3D maps, as well as pulmonary vein isolation when attempted, have yielded initial encouraging results. Testing of this system in the ventricles and coronary circulation remains to be carried out, as well as validation in clinical settings. It is anticipated that in the larger human atria and ventricles, extensive force gradients will be used to maintain contact with ridges and other difficult parts of cardiac anatomy. Moreover, three distinguishing features of the CGCI MNS may translate into better clinical outcomes when future clinical trials in similar patient populations are performed:

- enhanced maximal generated magnetic field forces (up to 0.15T);
- the ability to maintain the catheter tip at the desired target point; and
- the ability to repeatedly return the catheter tip to the selected target site despite cardiac motion and anatomic irregularities.

The new, focused magnetic field concept minimises the parasitic external magnetic forces around and within a short distance of the system. This allows undisturbed use of other electronic medical equipment and obviates the need to shield the procedure room. Other technical advantages of the CGCI MNS over the Niobe MNS include:

- the use of electromagnets;
- rapid shaping of the magnetic field leading to realtime response and rapid catheter tip movement (a useful feature during long and complex procedures);
- a closed-loop servo-automated navigation enabling catheter displacement to continuously be adjusted for repetitive learned cardiac movements;
- anatomic barriers by the controller; and
- controller-enhanced catheter tip stability. This is achieved by keeping the position on a desired target using magnetic field adjustments.

Comparison of Remote and Manual Navigation

Any technical innovation has to prove superiority or at least non-inferiority to the gold standard. In patients with AVNRT, accessory pathways or atrioventricular junctional ablation studies comparing Niobe MNS and conventional manual catheter manipulation have shown that fluoroscopy exposure time may be reduced, but total procedure time is the same or longer when using the MNS.[21,22,37,38] CTI radiofrequency ablation using MNS resulted in shorter fluoroscopy times but was associated with a significantly lower success rate, longer ablation times and higher radiofrequency settings.[9] These results suggest that Niobe MNS might be more beneficial for focal ablations compared with linear ones. RNS-guided CTI radiofrequency ablation also required shorter X-ray exposure (eight minutes) and radiofrequency duration compared with a conventional procedure. However, total procedure time was still longer than manual ablation.[29]

The apparent safety of Niobe MNS allows for performing pulmonary vein isolation using a retrograde approach, a technique otherwise impossible with conventional catheter manipulation.[23] On the other hand, Niobe MNS-guided pulmonary vein isolation was only achieved in 8% of cases using a non-irrigated 4mm tip catheter. The new, irrigated MNS catheter may yield better results.[3,8] One study reported long procedure times (>300 minutes) for RNS-guided pulmonary vein isolation.[4] This was opposed to another achieving RNS-guided pulmonary vein isolation using shorter procedure times (180 minutes), limited fluoroscopy and similar success rates to conventional ablation approaches.[30] With regards to ventricular tachycardia radiofrequency ablation, the endo- and epicardial Niobe MNS-guided approach using the irrigated catheter showed similar success rates (≥85%) to manual ablation and shorter fluoroscopy time (26 minutes), but was associated with longer procedure (three hours) and radiofrequency times (33 minutes).[26]

Based on the preponderance of published studies using the clinically available RNS and MNS, X-ray exposure appears to be decreased but procedure times have not been significantly reduced. At times they have even been prolonged. At least part of the additional procedure time may be related to pre-procedure preparations of the systems, including the registration and positioning of the magnets for MNS, non-realtime movement of the catheter with the Niobe MNS and flushing of sheathes and gaining trans-septal access for RNS. A 'learning curve' for new technologies also needs to be taken into account. Moreover, working remotely does not mean only being remote from the X-ray source but also from the patient. This might entail the risk of not noticing a potential deterioration in the patient's clinical status or hearing steam-pops. Careful nursing or the use of proper patient surveillance equipment (intercommunications and video surveillance) is therefore mandatory. Data comparing Amigo-guided treatment with conventional manipulation are based on one animal study. The Amigo system was as effective as conventional manipulation in remotely and safely positioning the tip of a standard, commercially available electrophysiology catheter within millimetres of target sites typically evaluated during an electrophysiology study. The system provides and maintains the appropriate tissue contact necessary to obtain pacing thresholds equivalent to those obtained with manual catheter manipulation.[5] Similar clinical data comparing CGCI MNS-guided procedures with conventional manipulation are not yet available. One can conclude that experience with remote navigation is still preliminary and that a conclusion about long-term success cannot yet be made. Nowadays, economic considerations are increasingly influencing the physician's decisions on the use of healthcare resources. Both clinically available systems substantially add to the cost of the procedure. Therefore, it remains to be determined whether the potential benefits will outweigh this investment.

Future Directions

Accurate and reasonably rapid mapping of a cardiac chamber using an automated mapping mode would be a welcome feature for any remote magnetic or mechanical navigation system. While both systems have made some progress in this direction, they have yet to demonstrate the functionality of this feature. For the existing RNS, it will be necessary to reduce the sheath diameter and extend its length in order to enhance the safety of the procedure and extend the system's applicability to ventricular arrhythmias. In order to decrease procedure cost, an inexpensive non-steerable irrigated tip catheter that can be used with RNS should be developed. Remote navigation systems may be used in the future in conjunction with various ablation balloon technologies, which are limited in application to pulmonary vein isolation. Remote navigation of catheters could then enhance the efficacy of vein isolation and provide the necessary navigational capabilities to create additional lesion sets in the treatment of non-paroxysmal AF.

Conclusion

Extending the spectrum of indications for catheter ablation has increased the complexity of procedures. Two clinically tested, remote navigation systems were developed to facilitate mapping, increase catheter accuracy and stability and reduce the physician's X-ray burden. Both systems have shown feasibility in the treatment of several cardiac arrhythmias, but have yet to convincingly demonstrate superiority over existing manual catheter manipulation techniques. A new MNS has been designed to overcome some of the shortcomings of the existing MNS and has shown promise in animal experiments. The system is now being tested in a clinical trial. A new RNS is also currently undergoing its first clinical trial. ■

1. Ouyang F, Bänsch D, Ernst S, et al., Complete isolation of left atrium surrounding the pulmonary veins: new insights from the double-Lasso technique in paroxysmal atrial fibrillation, *Circulation*, 2004;110:2090–6.
2. Faddis MN, Blume W, Finney J, et al., Novel, magnetically guided catheter for endocardial mapping and radiofrequency catheter ablation, *Circulation*, 2002;106: 2980–5.
3. Pappone C, Vicedomini G, Manguso F, et al., Robotic magnetic navigation for atrial fibrillation ablation, *J Am Coll Cardiol*, 2006;47:1390–400.
4. Reddy VY, Neuzil P, Malchano ZJ, et al., View-synchronized robotic image-guided therapy for atrial fibrillation ablation: Experimental validation and clinical feasibility, *Circulation*, 2007;115:2705–14.
5. Knight B, Ayers GM, Cohen TJ, Robotic positioning of standard electrophysiology catheters: a novel approach to catheter robotics, *J Invasive Cardiol*, 2008;20(5):250–3
6. Ernst S, Ouyang F, Linder C, et al., Initial experience with remote catheter ablation using a novel magnetic navigation system: magnetic remote catheter ablation, *Circulation*, 2004;109:1472–5.
7. Chun KRJ, Wissner E, Koektuerk B, et al., Remote-controlled magnetic pulmonary vein isolation utilizing a new irrigated tip catheter in patients with atrial fibrillation, *Circ Arrhythm Electrophysiol*, 2010 July 7 [epub before print].
8. Di Biase L, Fahmy TS, Patel D, et al., Remote magnetic navigation: Human experience in pulmonary vein ablation, *J Am Coll Cardiol*, 2007;50:868–74.
9. Vollmann, Luthje L, Seegers J, et al., Remote magnetic catheter navigation for cavotricuspid isthmus ablation in patients with common-type atrial flutter, *Circ Arrhythm Electrophysiol*, 2009;2:603–10.
10. Al-Ahmad A, Grossman JD, Wang PJ, Early experience with a computerized robotically controlled catheter system, *J Interv Card Electrophysiol*, 2005;12:199–202.
11. Bernabei MA, Ugarte RC, Martin DT, et al., Robotic versus manual catheter ablation for atrial fibrillation, *Heart Rhythm*, 2009;6:S278.
12. Nguyen BL, Farkas L, Marx B, et al., The lobed magnetic field: initial animal validation of a new remote EP catheter guidance and control system, Abstract #4944, Heart Rhythm Society's 30th Annual Scientific Sessions, Boston, MA, 13–16 May 2009.
13. Faddis MN, Chen J, Osborn J, et al., Magnetic guidance system for cardiac electrophysiology: a prospective trial of safety and efficacy in humans, *J Am Coll Cardiol*, 2003;42:1952–8.
14. Chun JK, Schmidt B, Kuck KH, et al., Remote-controlled magnetic ablation of a right anterolateral accessory pathway-the superior caval vein approach, *J Interv Card Electrophysiol*, 2006;16:65–8.
15. Chun JK, Ernst S, Matthews S, et al., Remote-controlled catheter ablation of accessory pathways: results from the magnetic laboratory, *Eur Heart J*, 2007;28:190–5.
16. Ernst S, Ouyang F, Linder C, et al., Modulation of the slow pathway in the presence of a persistent left superior caval vein using the novel magnetic navigation system Niobe, *Europace*, 2004;6:10–4.
17. Burkhardt JD, Saliba WI, Schweikert RA, et al., Remote magnetic navigation to map and ablate left coronary cusp ventricular tachycardia, *J Cardiovasc Electrophysiol*, 2006;17:1142–4.
18. Mehta R, Hart DT, Nagra BS, et al., Successful ablation of focal left atrial tachycardia using Stereotaxis Niobe remote magnetic navigation system, *Europace*, 2008;10:280–3.
19. Aryana A, d'Avila A, Heist EK, et al., Remote magnetic navigation to guide endocardial and epicardial catheter mapping of scar-related ventricular tachycardia, *Circulation*, 2007;115:1191–200.
20. Thornton AS, Jordaens LJ, Remote magnetic navigation for mapping and ablating right ventricular outflow tract tachycardia, *Heart Rhythm*, 2006;3:691–6.
21. Davis DR, Tang AS, Gollob MH, et al., Remote magnetic navigation-assisted catheter ablation enhances catheter stability and ablation success with lower catheter temperatures, *Pacing Clin Electrophysiol*, 2008;31(7):893–8.
22. Moreno JL, Archondo T, Barrios R, et al., Ablation of atrioventricular nodal reentrant tachycardia using remote magnetic guidance (stereotaxis) requires lower temperature and power settings because of improved local contact, *Rev Esp Cardiol*, 2009;62(9):1001–1.
23. Miyazaki S, Nault I, Haissaguerre M, et al., Atrial fibrillation ablation by aortic retrograde approach using a magnetic navigation system, *J Cardiovasc Electrophysiol*, 2010;21(4):455–7.
24. Di Biase L, Burkhardt JD, Lakkireddy D, et al., Mapping and ablation of ventricular arrhythmias with magnetic navigation: comparison between 4 and 8-mm catheter tips, *J Interv Card Electrophysiol*, 2009;26(2):133–7.
25. Haghjoo M, Hindricks G, Bode K, et al., Initial clinical experience with the new irrigated tip magnetic catheter for ablation of scar-related sustained ventricular tachycardia: a small case series, *J Cardiovasc Electrophysiol*, 2009;20(8):935–9.
26. Di Biase L, Santangeli P, Astudillo V, et al., Endo-epicardial ablation of ventricular arrhythmias in the left ventricle with the remote magnetic navigation system and the 3.5 mm open irrigated magnetic catheter: results from a large single center case-control series, *Heart Rhythm*, 2010;7(8):1029–35.
27. Saliba W, Cummings JE, Oh S, et al., Novel robotic catheter remote control system: feasibility and safety of transseptal puncture and endocardial catheter navigation, *J Cardiovasc Electrophysiol*, 2006;17:1102–5.
28. Kanagaratnam P, Koa-Wing M, Wallace DT, et al., Experience of robotic catheter ablation in humans using a novel remotely steerable catheter sheath, *J Interv Card Electrophysiol*, 2008;21:19–26.
29. Steven D, Rostock T, Servatius H, et al., Robotic versus conventional ablation for common-type atrial flutter: a prospective randomized trial to evaluate the effectiveness of remote catheter navigation, *Heart Rhythm*, 2008;5(11):1556–60.
30. Willems S, Steven D, Servatius H, et al, Persistence of pulmonary vein isolation after robotic remote-navigated ablation for atrial fibrillation and its relation to clinical outcome, *J Cardiovasc Electrophysiol*, 2010 Apr 23 [epub ahead of print].
31. Yokoyama K, Nakagawa H, Shah DC, et al., Novel contact force sensor incorporated ion irrigated radiofrequency ablation catheter predicts lesion size and incidence of steam pop and thrombus, *Circ Arrhythm Electrophysiol*, 2008;1:354–62.
32. Thornton AS, Res J, Mekel JM, et al., Use of advanced mapping and remote magnetic navigation to ablate left ventricular fascicular tachycardia, *Pacing Clin Electrophysiol*, 2006;29:685–8.
33. Gallagher P, Martin L, Angel L, et al., Initial clinical experience with cardiac resynchronization therapy utilizing a magnetic navigation system, *J Cardiovasc Electrophysiol*, 2007;18:174–80.
34. Ramcharitar S, Patterson MS, van Geuns RJ, et al., A randomised controlled study comparing conventional and magnetic guidewires in a two-dimensional branching tortuous phantom simulating angulated coronary vessels, *Catheter Cardiovasc Interv*, 2007;70:662–8.
35. Kolb C, Luik A, Hessling G, et al., Magnetic catheter navigation system interference with a dual-chamber pacemaker, *J Cardiovasc Electrophysiol*, 2007;18:892–3.
36. Crick SJ, Sheppard MN, Ho SY, et al., Anatomy of the pig heart: comparisons with normal human cardiac structure, *J Anat*, 1998;193:105–19.
37. Kerzner R, Sánchez JM, Osborn JL, et al., Radiofrequency ablation of atrioventricular nodal reentrant tachycardia using a novel magnetic guidance system compared with a conventional approach, *Heart Rhythm*, 2006;3:261–7.
38. Wood MA, Orloy M, Ramaswamy K, et al., Remote magnetic versus manual catheter navigation for ablation of supraventricular tachycardias: a randomized, multicenter trial, *Pacing Clin Electrophysiol*, 2008;31(10):1313–21.